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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,888	03/06/2002	Minoru Takebe	211A 3161 PCT	2747

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EXAMINER

LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,888

Applicant(s)

TAKEBE ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed 8/12/04 have been entered. Claims 8, 14, and 16 have been canceled. Claims 1-7, 9-13, and 15 have been amended, are pending in the application, and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 8/12/04 response would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-13, and 15 are newly rejected under 35U.S.C. 112 first paragraph, because the specification as originally filed does not describe the invention as now claimed. The original disclosure fails to disclose an "isolated" isoflavone aglycone as now claimed. The subject matter is now considered to be new matter.

MPEP 2163.02 teaches that "WHENEVER THE ISSUE ARISES, THE FUNDAMENTAL FACTUAL INQUIRY IS WHETHER A CLAIM DEFINES AN INVENTION THAT IS CLEARLY CONVEYED TO THOSE SKILLED IN THE ART AT THE TIME THE APPLICATION WAS FILED...IF A CLAIM IS AMENDED TO INCLUDE SUBJECT MATTER, LIMITATIONS, OR TERMINOLOGY NOT PRESENT IN THE APPLICATION AS FILED, INVOLVING A DEPARTURE FROM, ADDITION TO, OR DELETION FROM THE DISCLOSURE OF THE APPLICATION AS FILED, THE EXAMINER SHOULD CONCLUDE THAT THE CLAIMED SUBJECT MATTER IS

NOT DESCRIBED IN THAT APPLICATION". MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added). The specification as originally filed describes a mixture of fermented soy materials with concentrated isoflavone aglycone, and fails to teach isolated isoflavone aglycone or using such for feeding the animals. Thus, the amendment is a departure from or an addition to the disclosure of the application as filed, accordingly, it introduces new matter into the disclosure.

For reasons set forth above, the amendment filed 8/12/04 is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

To the extent that the claimed methods are not described in the instant disclosure, claims 1-7, 9-13, and 15 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and following.

In the response, Applicants pointed to pages 3-6 of the specification and argue that it is described that the high percentage of daizein namely 70% of the isoflavone aglycone has estrogen-like activity and binds with the estrogen receptor to activate the fusion protein of step 3.

In response, the specification (pages 3-6) contemplates the possible mechanisms underlying the effects of the isoflavone aglycone-concentrated material. The specification teaches exposing rats to radiation followed by bone marrow transplantation (BMT), and then feeding different groups of rats with regular food or food having concentrated isoflavone aglycone. The specification teaches that rats with concentrated isoflavone aglycone, particularly at higher doses, would have higher numbers of spleen colonies post-BMT (figures 4, 7, 10, 14). However, the specification fails to teach whether the slightly increased spleen cell colonies are the results of direct effect of isoflavone aglycone on stem cells, and it fails to show any direct effect on the characteristics of any type of the stem cell itself, particularly considering that various types of somatic stem cells have very different characteristics compared to hematopoietic stem cells.

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In view of the state of the art and the knowledge of the skilled in the art, it is known that isoflavone aglycones have health-promoting effect in general such as taught by Kelly et al (US 6,642,212), and Takebe et al (US 6045819 and 6303161). However, it is unknown and the specification fails to teach whether the increased spleen cell colonies are the direct effect on stem cells, or indirect effects on other *in vivo* factors such as cytokines, cell growth factors, or resulting from promoting general health conditions. Accordingly, the specification fails to provide an enabling disclosure for what is now claimed.

Accordingly, for reasons of record and those set forth *supra*, the rejection stands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to the claim recitation, "stem cell-augmenting" material, and in what sense it "augments" the stem cell, applicants point to paragraph 4 of page 3 in the specification. However, this paragraph reads "stem cells are augmented by the activity of daizein", it does not define in what characteristics the stem cells have been augmented. Hence, the metes and bounds of the claims are unclear. MPEP states, Claims must, under modern claim practice, stand alone to define invention, and incorporation into claims by express reference to specification and/or drawings is not

permitted except in very limited circumstances; thus, claims in utility applications that define invention entirely by reference to specification and/or drawings, known as "omnibus" or "formal" claims, are properly rejected under 35 USC 112, paragraph 2, as failing to particularly point out and distinctly claim invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

The prior rejection of Claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by *Luksas et al* (USP 3,878,302), is withdrawn because the disclosed material does not contain at least 70wt% daizein.

The prior rejection of Claims 1-6 and 9-12 under 35 U.S.C. 102(b) as being anticipated by *Groben et al* (USP 4,214,008), is withdrawn because the disclosed material does not contain at least 70wt% daizein..

Prior rejection of Claims 1-6 and 9-12 under 35 U.S.C. 102(e) as being anticipated by *Bojrab et al* (USP 6,641,808), is withdrawn because the disclosed material does not contain at least 70wt% daizein.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 5,885,632).

Takebe et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated by hydrolysis (claims 7-10), wherein said isoflavone aglycone is comprised of 70-100% daizein (table 3). Thus, *Tabete et al* anticipate instant claims.

In the response, applicants argue that table 3 relates to daidzein and does not state the total amount of isoflavone aglycones from which some one could compute a total percentage.

The arguments have been fully considered but found not persuasive. As an initial matter, the claims require total amount of daizein in the isoflavone compound, not total amount of isoflavone aglycones. To this end, it is noted the cited '632 patent clearly states that table 3 as well as table 2 "shows contents of isoflavone compounds" (column 7), wherein table 3 particularly shows that the isoflavone compound is comprised of 70-100% of daizein after hydrolysis. Thus, the amount of daizein in the isoflavone compound is fully taught in the cited patent.

Accordingly, the rejection stands.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 6,045,819).

Takebe et al teach a material comprising isoflavone aglycone (claim 7), wherein the aqueous extract is further concentrated by hydrolysis (claim 1), wherein said isoflavone aglycone is comprised of >70% daizein (table 5). Thus, *Tabete et al* anticipate instant claims.

In the response, applicants argue that the '819 patent is limited to daidzein and does not state the total amount of isoflavone aglycones from which some one could compute a total percentage.

The arguments have been fully considered but found not persuasive. As an initial matter, a search in Registry database would not yield any hit for the term "daizein", whereas the term "daidzein" yield 57 hits. This indicates that daizein is not an art-recognized term. Since instant applicant is a common inventor in the cited patent, unless the applicant can provide the difference in chemical structure, the two terms are treated equal for the sake of a compact prosecution. Secondly, assuming daizein and daidzein are structurally different, it is noted that since the starting materials and process of hydrolysis are the same for the above cited '632 patent and instant cited '819 patent, the contents of isoflavone compounds of the '632 patent would inherently contains 70-100wt% of daizein post-hydrolysis.

Accordingly, the rejection stands.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Takebe et al* (USP 6,303,161).

Takebe et al teach a material comprising isoflavone aglycone (table 4), wherein the aqueous extract is further concentrated by hydrolysis (claim 1), wherein said isoflavone aglycone is comprised of >70% daizein (tables 4, 5). Thus, *Tabete et al* anticipate instant claims.

Applicants presented the same arguments as discussed above, which have been addressed above, and will not be reiterated.

The prior rejection of Claims 1-7, 9-13, 15 under 35 U.S.C. 102(e) as being anticipated by *Obata et al* (USP 6,444,239), is withdrawn because the isoflavone aglycone contains less than 70% of daizein.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Kelly et al* (USP 6,642,212).

Kelly et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated (column 12, line 57), wherein said isoflavone aglycone is comprised of 95% daidzein (genistein:diadzein=1:19, claim 13). Thus, *Kelly et al* anticipate instant claims.

In the response, applicants argue that the teaching of *Kelly et al* is limited to daidzein, not daidzein, and the weight cannot be computed.

In response, as discussed above, it is applicant's duty to distinguish the daidzein from daizein, since the claimed daizein is not an well-recognized term in the art. *Kelly et al* have disclosed the contents of the isoflavone compound as containing 95% of daidzein, and thus there is no need to further compute. Accordingly, for reasons of record and set forth foregoing, the rejection stands.

Claims 1-7, 9-13, 15 stand provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/284,935 which has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Applicants argue that the cited patent application does not teach the high percentage of daizein, namely 70%.

In response, since the starting materials and the process of hydrolysis are the same for the above cited '632 patent and instant cited patent application, and thus, the contents of isoflavone compounds of the cited application would inherently contains 70-100wt% of daizein post-hydrolysis, and they further share the same function, i.e. both promoting proliferation of lactic acid bacteria. Accordingly, the rejection stands.

Claims 1-7, 9-13, 15 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Each of the above cited patents (5,885,632; 6,045,819; and 6,303,161) and the co-pending application have a different inventive entity compared to the instant application, but they anticipate instant claims, thus it is unclear who is the real inventor.

Applicants argue that different applications claim different subject matter.

In response, for reasons above discussed in details under each of the rejections, this rejection stands.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The prior rejection of Claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of U.S.

Patent No. 5,885,632, is withdrawn in view of the terminal disclaimer.

The prior rejection of Claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,045,819, is withdrawn in view of the terminal disclaimer.

The prior rejection of Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161, is withdrawn in view of the terminal disclaimer.

The prior rejection of Claims 1-7, 9-13, 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent Application No. 09/284,935, is withdrawn in view of the terminal disclaimer.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

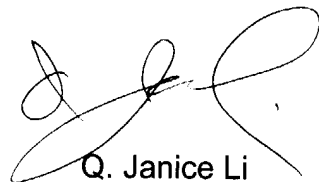
Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Q. Janice Li
Primary Examiner
Art Unit 1632


October 29, 2004